K041807

JUL 2 2 2004

Appendix E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitted by:

Name:	Medicsight PLC.
Address:	46 Berkeley Square London W1J 5AT UK
Telephone:	44 (0) 207 598 4070
Facsimile:	44 (0) 207 598 4071
Contact:	Carol MacDonald, RA QA Director
Date of summary:	1st July 2004

Device Information:

Trade Name:	Lung CAR™ Release 1.1
Common Name:	Medical imaging software for CT scanners
Classification Name:	Computed Tomography X-Ray System, Accessory
Regulation Number:	892.1750

Predicate Devices:

Medicsight Lung CAR 1.1 is substantially equivalent to the following devices:

Manufacturer	Device	510(k) No.
MEDICSIGHT	MEDICLUNG 1.0	K033412
SIEMENS	LUNGCARE CT (with extended functionality NEV)	K033374
GE	ADVANCED LUNG ANALYSIS	K013381

Device Description:

Lung CAR™ (Computer Assisted Reader) 1.1 is a software tool designed to assist radiologists and other clinicians in the evaluation of nodules and other lesions in the lug. The software allows the user to select Regions of Interest either manually or by selecting a single or double seed point, followed by semi-automatic detection of the ROI boundary. It provides 2D and 3D visualisation of nodules and other lesions, and measurement of nodule characteristics such as size and volume. The further features of Lung CAR™ 1.1 as compared to the cleared device are a series of filters, the results of which are presented in a Joint Reader filter view (enhanced and non-enhanced data viewed simultaneously). These filters are an edge enhancement filter, noise removal filters and a sphericity filter. The sphericity filter enhances structures of images with spherical elements within certain Hounsfield Unit (HU) ranges that are defined by the user. This enhancement can aid the user when looking at a highlighted area (sphere) as a potential spherical nodule.

Intended Use:

Lung CAR I.1 is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the lung derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of lung lesions (e.g. nodules). The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting either a single or double seed point followed by interactive fine-tuning the boundaries of the ROI. Lung CAR I.1 provides quantative information for measurement of lesion volume and other measured characteristics over time allowing the user to review and track any changes in the physician-indicated nodules or lesions.

Lung CAR 1.1 contains additional imaging tools which allow enhancement of specified features, and which the clinician can view simultaneously with the non-enhanced view.

Comparison to Predicate Device:

As in the predicate devices, MedicLung 1.0, GE ALA and Siemens LungCare CT NEV, Lung CAR1.1 assists users in assessing CT images for the identification and evaluation of nodules and other lesions in the colon.

Test data are provided to validate the performance of the system and its substantial equivalence to the predicate devices. The functional features and the intended use of Lung CAR 1.1 are substantially equivalent to the predicate devices. The modifications to the original device did not introduce any new potential safety risks.

Safety:

A comprehensive hazard analysis was carried out on Lung CAR 1.1, which concluded that any residual risks were as low as reasonably practicable and judged as acceptable when weighed against the intended benefits of use of the system.

Conclusion:

Lung CAR 1.1 does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices. Lung CAR 1.1 is therefore substantially equivalent with respect to safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2 2004

Ms. Carol MacDonald
Regulatory & Quality Director
Medicsight, PLC
46 Berkeley Square
London, W1J 5AT
UNITED KINGDOM

Re: K041807
Trade/Device Name: Medicsight Lung CAR 1.1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: July 1, 2004
Received: July 6, 2004

Dear Ms. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041807

Device Name: Medicsight Lung CAR 1.1

Indications for Use:

Lung CAR I.1 is a PC-based, stand-alone, non-invasive, image analysis software application for the display and visualization of 2D and 3D medical image data of the lung derived from CT scans, for the purpose of assisting radiologists and other clinicians in the evaluation of lung lesions (e.g. nodules). The software provides functionality for the user to extract the region of interest (ROI) either manually using a drawing tool, or "semi-automatically" through the user selecting either a single or double seed point followed by interactive fine-tuning the boundaries of the ROI. Lung CAR I.1 provides quantative information for measurement of lesion volume and other measured characteristics over time allowing the user to review and track any changes in the physician-indicated nodules or lesions.

Lung CAR 1.1 contains additional imaging tools which allow enhancement of specified features, and which the clinician can view simultaneously with the non-enhanced view.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Prescription Use ✓

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041807